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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT

PAPER NUMBER

1795

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,830	Applicant(s) ANSELMETTI ET AL.	
	Examiner ALEX NOGUEROLA	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/29/2009 (amendment).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-10 and 12-18 is/are pending in the application.
- 4a) Of the above claim(s) 13-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-10 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of May 29, 2009 does not render the application allowable. Applicant asserts that Koutny does not disclose a UV source exhibiting an energy density from 1 to 500 mW per cm², as measured at a surface of the separation medium. As a first matter, the Examiner does not accept Applicant's calculation of the energy density of the UV source used by Koutny. Applicant appears to be making unwarranted assumptions, namely that the "UV lamp emits a light having about 10 W in the line spectrum, about 5% of which is at 254 nm, i.e. 500 mW" and that the energy density at the filter should be divided by 225 to determine what the energy density will be at the surface of the gel. In any event, even if Applicant can establish that his calculation is reasonably accurate, to use a more powerful UV lamp is clearly obvious. Koutny states, "Exposure times under 1 min are clearly sufficient, particularly if more intense lamps are used" and "It should be noted, however, that both on-line techniques could benefit from a more intense light source and a better spectral match with the absorption bands, as well as longer signal integration times." See the first full paragraph in the first column on page 186 and the first paragraph of **Conclusion** on page 187. In this regard it should be noted that at the time of the invention there were

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available light sources capable of emitting light in the wavelength range of 190 nm to 360 nm in the range of 10 W/cm^2 to 10^{11} W/cm^2 . See Ota et al. US 5,483,038 col. 02:12-21. Thus, barring a contrary showing, the claimed energy density range is just optimization.

Turning to Hassard, Applicant asserts, "... Hassard requires that the UV detector is situated on another side of the separation medium in relation to the UV source so that the UV detector can measure the fluorescent light transmitted through the separation medium containing the UV-absorbing molecules, ..." However, Hassard discloses in col. 08:18-26

20 In an alternative arrangement, the UV source could be mounted to a transverse scanning assembly (not shown) secured to the lid 720. In that arrangement, the UV source would scan across the sample while the detector, within the base portion 710, could remain stationary. It would also be possible for both the UV source and the detector to be mounted to scanning assemblies, both assemblies scanning across the gel at the same speed. In either the preferred or in

Thus Hassard discloses having the UV source and UV detector situated on the same side of the separation medium.

Turning to Schrifman, Applicant asserts, "... it would be clear to a person skilled in the art of UV densitometry that the UV detector must be situated on the another side of the separation medium in relation to the UV source so that the UV detector can measure the UV light transmitted through the separation medium containing UV-

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absorbing substances.” The Examiner respectfully disagrees. Assuming, arguendo, that in Schrifman the UV detector is situated on the another side of the separation medium in relation to the UV source, as shown by Harju et al US 5,780,857, the abstract and Figure 1, an alternative TLC UV detection system in which the UV detector is situated on the same side of the separation medium in relation to the UV source was known. The substitution of the detection system of Harju for that used in Schrifman is just substitution of one known element for another with predictable results.

For the reasons listed above the Examiner view the prior art as still reading on the claimed invention.

Status of the Rejections pending since the Office action of January 02, 2009

2. All previous rejections are withdrawn.

Claim Rejections - 35 USC § 112

3. Claims 1, 2, 5-10, and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application

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was filed, had possession of the claimed invention. Claim 1 requires that "... the excitation light provided from the UV source exhibits an energy density from 1 to 500 mW per cm^2 , as measured at a surface of the separation medium." No support has been cited or found for this limitation. Example 1 in the specification discloses a power density of 40 mW/ cm^2 . So this is apparently the highest energy density that can be claimed. Since claims 2 and 5-12 depend from claim 1 they will also have this new matter issue.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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5. Claims 1, 2, 5, 6, 8, 9, 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koutny et al. "On-Line Detection of Proteins in Gel Electrophoresis by Ultraviolet Absorption and by Native Fluorescence Utilizing a Charge-Coupled Device Imaging System," Anal. Chem. 1993, 65, 183-187 ("Koutny") in view of Ota et al. US 5,483,038 ("Ota").

Addressing claim 1, Koutny discloses a device for quantifying separable substances by measuring their inherent fluorescence when excited with UV radiation (title), the device comprising

a) a UV source (UV – Figure 1) for providing excitation light in the wavelength range from 140 to 320 nm (last paragraph in the first column on page 184 "For native fluorescence ... hand-held UV lamp, operating at 254 nm);

b) a separation medium (GEL – Figure 1) for providing a flat-bed electrophoretic separation of electrically charged substances (Figures 1 and 2);

c) regions of substances that are distributed in the separation medium (2), the substances distributed in the regions being separated and unlabelled, and the substances distributed in the regions emitting upon excitation by excitation light provided from the UV source (the first full paragraph in the first column on page 184 – "In all cases, 5 μ l of sample was loaded in each well" and Figure 2) a UV fluorescence radiation in a wavelength range from 150 to 400 nm (the first full paragraph in the second column on page 183 and the last paragraph in the first column on page 185);

d) a UV detector (CCD – Figure 1) for detecting the UV fluorescence radiation (the first full paragraph in the second column on page 183 and the last paragraph in the

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first column on page 185), the UV detector being located on a same side of the separation medium as the UV source (Figure 1); and

e) optical or optoelectronic components for filtering, guiding and/or amplifying the excitation radiation and the fluorescence radiation (DF, QL – Figure 1).

Koutny does not mention whether the excitation light provided by the UV source exhibits an energy density from 1 to 500 mW per cm². However, the limitation is either implied in Koutny or obvious. It is implied because based on a 30-W UV lamp and a

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2 square inch band pass filter with 13% transmittance (last paragraph in the first column on page 184) the energy density of the UV system in Koutny is $(30 \times 13\%)W / 4 \text{ in}^2 = 0.96 W / \text{in}^2 = 0.15 W / \text{cm}^2 = 150 \text{ mW} / \text{cm}^2$, which is within the claimed range. Even if Applicant can establish that the energy density is actually lower (the Examiner does not yet accept the calculation made by Applicant) the claimed range is obvious over Koutny because Koutny states, "Exposure times under 1 min are clearly sufficient, particularly if more intense lamps are used" and "It should be noted, however, that both on-line techniques could benefit from a more intense light source and a better spectral match with the absorption bands, as well as longer signal integration times." See the first full paragraph in the first column on page 186 and the first paragraph of **Conclusion** on page 187. In this regard it should be noted that at the time of the invention there were available light sources capable of emitting light in the wavelength range of 190 nm to 360 nm in the range of $10 W/\text{cm}^2$ to $10^{11} W/\text{cm}^2$. See Ota col. 02:12-21. Thus, barring a contrary showing, the claimed energy density range is just optimization and substituting one known element (UV light source) for another with predictable results.

Addressing claim 2, for the additional limitation of this claim see the last paragraph in the first column on page 184 (UV lamp).

.
Addressing claims 5 and 6, for the additional limitation of these claims see the first paragraph in the first column on page 184 (agarose).

Addressing claim 8, for the additional limitation of this claim note PT and QP in Figure 1.

Addressing claim 9, for the additional limitation of this claim see the first full paragraph in the second column on page 183, which mentions tryptophan and tyrosine groups, and the ACS Registry entries for tryptophan and tyrosine, which show the chemical structures of these compounds.

Addressing claim 10, for the additional limitation of this claim see the first full paragraph in the second column on page 183

Addressing claim 12, for the additional limitation of this claim see Figure 1 (CCD).

6. Claims 1, 2, 5, 6, 8, 9, 10, and 12 are rejected under 35 U.S.C. 103(a) as being anticipated by Hassard et al. US 6,613,210 B1 (“Hassard”) in view of Ota.

Addressing claim 1, Hassard discloses a device for quantifying separable substances by measuring their inherent fluorescence when excited with UV radiation (abstract and col. 03:28-35), the device comprising

a) a UV source (121 – Figure 12) for providing excitation light in the wavelength range from 140 to 320 nm (col. 03:63 – col. 04:03 and col. 04:23-30);

b) a separation medium (col. 09:03-11) for providing a flat-bed electrophoretic separation of electrically charged substances (col. 09:03-11);

c) regions of substances that are distributed in the separation medium (2), the substances distributed in the regions being separated and unlabelled, and the substances distributed in the regions emitting upon excitation by excitation light provided from the UV source (col. 09:15-26 and col. 03:45-54) a UV fluorescence radiation in a wavelength range from 150 to 400 nm (col. 04:36-47);

d) a UV detector (130) for detecting the UV fluorescence radiation (col. 09:12-15), the UV detector being located on a same side of the separation medium as the UV source (col. 08:18-25, especially “It would also be possible for both the UV source and the detector to be mounted to scanning assemblies, ...”); and

e) optical or optoelectronic components for filtering, guiding and/or amplifying the excitation radiation and the fluorescence radiation (128, 129).

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Hassard does not mention whether the excitation light provided by the UV source exhibits an energy density from 1 to 500 mW per cm². However, the limitation is obvious because Hassard disclose that the light source may be “.. a UV lamp or a deuterium or discharge lamp. Alternatively, it could comprise a laser capable of operating in the range between 220 nm and 180 nm, or even a diode.” See col. 0945-49. This a wide range of UV light sources is contemplated. In this regard it should be noted that at the time of the invention there were available light sources capable of emitting light in the wavelength range of 190 nm to 360 nm in the range of 10 W/cm² to 10¹¹ W/cm². See Ota col. 02:12-21. Thus, barring a contrary showing, the claimed energy density range is just optimization and substituting one known element (UV light source) for another with predictable results.

Addressing claim 2, for the additional limitation of this claim see col. 09:03-06.

Addressing claims 5 and 6, for the additional limitations of these claims see col. 05:28-29.

Addressing claim 8, for the additional limitation of this claim see col. 09:03-11.

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Addressing claims 9 and 10, for the additional limitation of these claims see col. 04:23-31.

Addressing claim 12, for the additional limitation of this claim see col. 04:36-47.

7. Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being anticipated by Schrifftman, "Analysis of Pharmaceuticals by Ultraviolet Densitometry on Thin-Layer Chromatograms I – Parabens in Gels and Creams," Journal of Pharmaceutical Sciences (1968), 57(10), 1760-3 ("Schriftman") in view of Harju et al. US 5,780,857 ("Harju") and Ota.

. Addressing claim 1, Schrifftman discloses a device for quantifying separable substances by measuring their inherent fluorescence when excited with UV radiation (abstract), the device comprising

a) a UV source (abstract; **Experimental – Equipment** on page 1761; and **Summary** on page 1762) for providing excitation light in the wavelength range from 140 to 320 nm (254 mμ in **Experimental – General Procedure** on page 1761);

b) a separation medium (at least silica thin layer gels - abstract) for providing a flat-bed chromatographic separation of electrically charged substances (abstract; that

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the substances are electrically charged is an intended use for which the separation medium is capable performing);

c) regions of substances that are distributed in the separation medium, the substances distributed in the regions being separated and unlabelled, and the substances distributed in the regions emitting upon excitation by excitation light provided from the UV source (Figure 1) a UV fluorescence radiation in a wavelength range from 150 to 400 nm (485 m μ in **Experimental – General Procedure** on page 1761);

d) a UV detector for detecting the UV fluorescence radiation (abstract; **Experimental – Equipment** on page 1761; and **Experimental – General Procedure** on page 1761); and

e) optical or optoelectronic components for filtering, guiding and/or amplifying the excitation radiation and the fluorescence radiation (485 m μ color filter in **Experimental – General Procedure** on page 1761).

Schriftman does not mention whether the excitation light provided by the UV source exhibits an energy density from 1 to 500 mW per cm². However, the limitation is obvious because at the time of the invention there were available light sources capable of emitting light in the wavelength range of 190 nm to 360 nm in the range of 10 W/cm² to 10¹¹ W/cm². See Ota col. 02:12-21. Thus, barring a contrary showing, the claimed energy density range is just optimization and substituting one known element (UV light source) for another with predictable results.

Schriftman also does not mention having the UV detector being located on a same side of the separation medium as the UV source. Assuming that this is not so, Harju discloses an apparatus for imaging biochemical samples on substrates, such as electrophoretic gels or TLC plates, wherein the UV detector is located on a same side of the separation medium as the UV source. See the abstract and Figure 1. Barring a contrary showing, to arrange the UV detector and UV source as claimed is just substitution of one known element (UV detection system) for another with predictable results.

Addressing claim 7, for the additional limitation of this claim see the title and abstract.

Final Rejection

8. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguera/
Primary Examiner, Art Unit 1795
August 19, 2009